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10/037,573	01/03/2002	Christopher J. Milley	787446-2002	6517

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	7

DATE MAILED: 04/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/037,573	Milley et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 13, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above, claim(s) *11-19* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction

Applicant's election with traverse of Group I, Claims 1-10, in Paper No. 5 is acknowledged. The traversal is on the ground that a proper search to determine the patentable novelty of the method of rending a hydrophobic nutritional compound water dispersible of claims 1-19 (Group II) would include the resultant aqueous suspension of the hydrophobic nutrient as defined in claims 1-10 (Group I). This is not found persuasive because In the instant case, the product as claimed can be made by another and materially different process. For example, in U.S. Patent No. 6,294,192, Patel teaches a method of rendering a hydrophobic nutritional compound water compound water dispersible comprising different process steps and different ingredients than those instantly claimed in the disclosed invention. See entire document.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4 and 9 are rejected under 35 U.S.C. 112, second paragraph as being

vague and indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Although not rising to the level of uncertainty, Claims 1 and 4 are rendered grammatically incorrect by misplaced punctuation. Applicant may overcome the rejection by deleting the comma that appears after "comprises" in line 1 of Claim 1, and by deleting the comma that appears after "phytostanol" in line 5 of Claim 4, respectively.

Although not rising to the level of uncertainty, Claim 1 is rendered grammatically incorrect by a misplaced punctuation in line 5. Applicant may overcome the rejection by replacing the colon that appears after "agent" with a semicolon.

Claim 3 recites the limitation "wherein the particles size of said fully dispersed uniform form ranges from 50 to 400 nm" in lines 1-2. The claim lacks clear antecedent basis for this limitation in the claim.

Claims 4 and 9 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C". See Ex parte Markush, 1925 C. D. 126 (Comm'r Pat. 1925). Applicant may overcome the rejection by deleting "e.g." in line 5 of Claim 4 because the term renders the claim indefinite; and, Applicant may overcome the rejection by replacing "a" with the in line 2 of Claim 9.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikkonen et al. (N).

Applicant claims an aqueous suspension of a hydrophobic nutrient which comprises the nutrient in ester form associated with a dispersion aid selected from the group consisting of a triglyceride, an essential oil extractive, night primrose oil, fish oil, and a mixture of any of the foregoing dispersion aids; a dispersion agent; and an aqueous medium into which said associated nutrient is suspended. Applicant further claims the suspension as defined in claim 1, wherein said associated nutrient is in a fully dispersed, uniform form in the aqueous medium. Applicant further claims the suspension as defined in claim 1, wherein said ester is an ester of a nutritional compound selected from the group consisting of (a) a phytosterol selected from the group consisting of stigmasterol, sitosterol, fucosterol, brassicasterol, campesterol, clionasterol, desmosterol, chalinosterol, poriferasterol, and any mixture of the foregoing phytosterols; (b) a phytostanol selected from the group consisting of α sitostanol or β sitostanol, campestanol,

brassicastanol, clionastanol, stigmastanol, desmostanol, chalinostanol, poriferastanol, 22, 23 dihydrobrassicastanol and any mixture of the foregoing phytostanols; (c) lutein; (d) Coenzyme $Q_{10;}$ (e) isoflavones; (f) and a mixture of any of the foregoing esters. Applicant further claims the suspension as defined in claim 1, wherein said triglyceride is selected from the group consisting of sunflower oil, soy bean oil, olive oil, a medium chain triglyceride selected from the group consisting of fatty acids ranging from C_6 to C_{12}, and a mixture of any of the foregoing triglycerides. Applicant further claims the suspension as defined in claim 1, wherein said essential oil extractive is one selected from the group consisting of orange oil, lime oil, clove oil, oregano oil, peppermint oil, cinnamon oil, and a mixture of any of the foregoing extractives. Applicant further claims the suspension as defined in claim 1, wherein said dispersion agent is selected from the group consisting of (a) lecithin, (b) a hydrocolloid, (c) a surfactant and (d) a mixture of any of the foregoing dispersion agents. Applicant further claims the suspension as defined in claim 7, wherein said lecithin is selected from the group consisting of lecithin derived from soybean and lecithin derived from egg.

Mikkonen teaches phytosterol and phytostanol esters, e.g., β-sitosterol and β-sitostanol esters, that have been modified so that the fat solubility of their derivatives are significantly increased in relation to free phytosterols and phytostanols (see page 7, lines 11-17). On page 10, lines 18-21, Mikkonen teaches that the compounds of his invention "are soluble and/or dispersible in water, ethanol and lipids, so that compounds according to this invention can at the same time be dissolved/dispersed in water and ethanol and dissolved in the fatty component of the product."

On page 15, lines 30-31, examples of plant sterol and/or plant sterols used in the making of the phytosterol esters and phytostanols taught by Mikkonen are sitosterol, stigmasterol, campesterol, brassicasterol, cycloartenol, 24-methylene cycloartenol and cyclobranol, etc. See also page 16 and 17, lines 1-17. Dietary fats used in the making of the Mikkonen' compositions are taught on page 17, lines 19-21, and include animal or milk fats, and plant oils such as rape seed, sunflower, olive and palm oil. Fat containing products, which are used in the making of the compositions taught by Mikkonen are taught on page 17, lines 28-33. Mikkonen teaches an aqueous suspension comprising an amino acid ester of a phytosterol and/or a phytostanol associated with a dispersion aid, a dispersion agent, and an aqueous medium into which the associated nutrient is suspended. For example, on page 39, in Example 29, Mikkonen teaches a composition comprising a β-sitosterol hemisuccinate (hydrophobic nutrient ester compound), mint oil (dispersion aid of an essential oil extractive), egg yolk (dispersion agent comprising lecithin), butter (dispersion aid containing triglycerides), cream (aqueous medium), and chocolate (dispersion aid containing triglycerides), alcohol (aqueous medium into which said associated nutrient is suspended). On pages 40-41, in Example 31, Mikkonen teaches a cream liqueur comprising a β-sitosterol hemisuccinate (hydrophobic nutrient ester compound), fat (dispersion aid containing a triglyceride), starch fluid sugar (dispersion aid of a hydrocolloid), and water and alcohol (aqueous medium).

The reference anticipates the claimed subject matter.

Claims 1, 2, 4-7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Philip (A).

Applicant's claimed invention of Claims 1, 2 and 4-7 was set forth above. Applicant further claims the suspension as defined in claim 7, wherein said surfactant is selected from the group consisting of cetylpyridinium chloride, polysorbate 80, sorbitan monosterate, a polyglycerol ester, a block copolymer of propylene oxide, ethylene oxide and a mixture of any of the foregoing surfactants.

Philip teaches lutein-fatty acid esters containing lutein dipalmitate and triglycerides, which are soluble in vegetable oils and which can be used in aqueous foods as dispersions as a colorant (see Column 2, lines 43-50). In Example 1, Philip teaches an aqueous composition comprising a lutein-fatty acid ester (hydrophobic nutrient in ester form associated with a C12 triglyceride, i.e., a triglyceride dispersion aid; see Table 1), mono- and diglycerides, Polysorbate 80 (dispersion agent; a surfactant), and ice cream (an aqueous medium into which the associated nutrient is suspended). In Example 2, Philip teaches dissolving hydrogenated vegetable oil, mono- and diglycerides, a lutein-fatty acid ester (hydrophobic nutrient in ester form associated with a C12 triglyceride, i.e., a triglyceride dispersion aid; see Table 1), in acetone (an aqueous medium into which the associated nutrient is suspended), which is mixed with ground Citrus Juice Sacs, dried, dispersed in water, and mixed with sucrose, citric acid, and orange oil to form an aqueous beverage.

The reference anticipates the claimed subject matter.

Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by van Amerongen et al. (D).

Applicant's claimed invention of Claims 1, 2, 4, 5, 7 and 8 was set forth above.

In Column 4, lines 64-67, to Column 5, lines 1-15 (Example 2a), van Amerongen teaches an aqueous suspension of sunflower oil (dispersion aid- triglyceride) enriched with esterified stanols, mixed with refined sunflower oil and rapeseed oil, and palm oil, and kernel oil to form a fat blend (triglycerides) dispersion aids); to this fat blend soybean lecithin (dispersion agent), monoglyceride, and beta-carotene solution were added; an aqueous solution of water, whey protein powder (a hydrocolloid) were added to the fat blend. In Column 6, lines 1-16, van Amerongen teaches a process of making a dressing comprising mixing water with flavor components, preservatives, thickeners and emulsifiers (dispersion agent), and adding a sunflower oil enriched stanol ester to obtain an oil mixture; to this oil mixture sunflower is added (dispersion agent- triglyceride), which is mixed in a colloid mixer. van Amerongen teaches, "A good and stable water continuous dressing enriched with 8% stanol equivalents (mainly present as C18:0 stanol esters) is obtained."

The reference anticipates the claimed subject matter.

Claims 1-5, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Emodi et al. (E).

Applicant's claimed invention of Claims 1-5, 7 and 10 was set forth above. Applicant further claims the suspension as defined in claim 7, wherein said hydrocolloid is selected from the group consisting of xanthan gum, starch, pectin, gelatin, guar gum, carrageenan, methylcellulose, hydroxypropyl cellulose and a mixture of the foregoing mixtures.

Emodi teaches an aqueous suspension of a hydrophobic nutrient comprising the instantly claimed ingredients. In Column 1, lines 53-67, Emodi teaches carotenoid coloring agents such as lutein and lower alkyl esters of hydroxyl- or carboxyl-containing members of this group such as the methyl and ethyl esters can be used in the making of his invention. In Column 3, lines 28-40, Emodi teaches liquid compositions comprising of either polysorbate 60 or preferably polysorbate 80 (dispersion agent- surfactant), monoglycerides of lower weight saturated coconut oil fatty acids, and coconut triglycerides (dispersion aid) to form a viscous liquid. See also Column 3, lines 63-67 to Column 4, lines 1-5. In Column 4, lines 21-45, Emodi teaches adding water to the viscous liquid. In another example as set forth in Column 4, lines 6-14, Emodi teaches adding to the viscous liquid, as set forth immediately above, a previously formed aqueous solution containing a soluble colloid forming agent, sugar and preservatives in the making of a water-soluble powdered product. In Column 2, lines 25-67, Emodi teaches using gelatin as a hydrocolloid in the making of the referenced composition. Emodi further teaches filtering the various liquids and powders to retain particles larger than 0.22 microns.

The reference anticipates the claimed subject matter.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Patrick et al. (O).

Applicant's claimed invention was set forth above.

Patrick teaches aqueous dispersions comprising plant sterols and other high melting lipids. The phytosterols and other high melting lipids used in the method of making the compositions taught by Patrick are present as finely divided particles having a size of 15 microns or less; and preferably 10 nanometers to 50 microns. See page 4, lines 2-3 and page 7, lines 35-36. Preferred phytosterols are beta-sitosterol, campesterol, stigmasterol, brassicasterol and ergosterol. High melting lipids taught by Patrick include sterolesters and stanolesters, triglycerides of vegetable oils, mono- and diglycerides (see page 4, lines 56-58). On page 5, lines 9-13, Patrick teaches that his invention may be applied to chemically modified phytostanols and chemically modified sterols, wherein the chemical modifications include esterification and interesterification. " Examples of phytostanols include campestanol, 22, 23 dihydrobrassicastanol, beta-sitostanol and clionastanol. Fatty acids esterified to the sterols include long and short chain fatty acids, i.e., C_1 to C_{22}." Patrick further teaches dispersing phytosterols or other high melting lipids in emulsifiers (dispersion agents), such as TWEENs™, especially polysorbate 60, and polyglyceryl esters, on page 5, lines 16-19. The aqueous dispersions may further include water (aqueous medium), gums, starches, gelatin (dispersion agent- hydrocolloids), milk and milk proteins (see page 5, lines

20-23; page 6, lines 9-31). On page 6, lines 32-44, Patrick teaches adding a fatty phase (dispersion aid-triglycerides), e.g., oils of sunflower, safflower, rapeseed, linseed, linola and/or soybean, to the referenced aqueous compositions. See Claims 1-11 and 25-31.

The reference anticipates the claimed subject matter.

Claims 1-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kropf et al. (B).

Applicant's claimed invention was set forth above.

Kropf teaches nanoscale esters of phytosterols such as ergosterols, campesterols, stigmasterols, brassicasterols, β-sitosterol and β-sitostanols with particle diameters of 10 to 300 nm, preferably 50 to 150 nm, which are used in the making of aqueous cosmetic and/or pharmaceutical preparations (see Column 1, lines 53-61; Column 2, lines 5-9; and, Column 3, lines 33-43). In Column 2, lines 10-33, Kropf teaches that use of phytosterol esters in association with fatty acids containing 12 to 18 carbons are preferred. In Column 2, lines 32-37, "These esters may be prepared both by direct esterification of the phytosterols with the fatty acids or by transesterification with fatty acid lower alkyl esters of triglycerides . . .". Kropf teaches several methods of making the referenced nanoparticle phytosterol esters. For example, one method involves rapid expansion of supercritical solutions: "To prevent the nanoparticles from agglomerating, . . . dissolve the starting material in the presence of suitable protective colloids or emulsifiers and/or to expand the critical solutions into aqueous and/or alcoholic solutions of the protective colloids or emulsifiers or into cosmetic oils which may in turn contain redissolved

emulsifiers and/or protective colloids. Suitable protective colloids are, for example, gelatine, casein, gum arabic, lysalbinic acid, starch and polymers, such as polyvinyl alcohols, polyvinyl pyrrolidones, polyalkylene glycols and polyacrylates." See Column 2, lines 39-53. The nanoscale esters taught by Kropf are surrounded by a protective colloid and/or an emulsifier (see Column 2 , lines 49-58). In another example, Kropf teaches that the nanoscale esters are dissolved in a solvent, e.g., vegetable oils, introduced into water or another non-solvent, optionally in the presence of a surface-active compound dissolved therein, wherein the nanoparticles are precipitated by the homogenization of the two immiscible solvents, in Column 2, lines 58-67. In Column 3, lines 33-43, Kropf further teaches that the nanoscale sterol esters can be use in the making of shampoos, lotions, foam baths or emollients that may contain surfactants, oils, emulsifiers, superfatting agents, perfume oils, etc. Examples of the dispersing aids and dispersing agents used in the making of the compositions taught by Kropf are set forth in Column 3, line to Column 6 in its entirety, and Column 10, lines 10-53. Examples of using the phytosterol particles taught by Kropf are exemplified in Table 2, in Column 11-14. For instance, composition 13, a foam bath, comprises a nanosterol ester of Example 1 (hydrophobic nutrient in ester form comprising β-sitosterol, campesterol and stigmasterol), melissa oil (dispersion aid- an essential oil extractive), Eumulgin® SE (dispersion agent- surfactant), polyglyceryl-2-dipolyhydroxystearate (dispersion agent- surfactant), and water.

The reference anticipates the claimed subject matter.

Claims 1, 2, 4, 5, 7, 9 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Yuan et al. (C).

Applicant's claimed invention was set forth above.

Yuan teaches compositions comprising phytosterols, e.g., sitosterol, sitosterin, campesterol, campesterol, stigmasterol, and mixtures thereof) that are dispersible in oil, water, or both water and oil (see Column 1, lines 27-46). In Column 3, lines 43-62, Yuan teaches that sterols esterified with fatty acids, as well as esters of sterols and stanols can be used in the making of the referenced compositions. In Column 4, lines 8-34, Yuan teaches that the composition of his invention comprises one or more fats, such as a liquid oil (soybean oil, sunflower oil) and triglycerides or fatty acids (dispersing aids). In Column 4, lines 35-65, Yuan further teaches that his compositions comprise emulsifiers (dispersing agents), such as polysorbate 80, polysorbate 60, sorbitan monostearate, DATEM, sodium stearyl lactylate. Finally, in Column 6, lines 8-21, Yuan teaches adding hydrocolloids to the referenced compositions. For example, xanthan gum, alginate, carrageenan, carboxymethyl cellulose, methylcellulose, guar gum, etc., and mixtures thereof are taught as hydrocolloids useful in the making of the Yuan' compositions. In Column 8, lines 30-60, (Example 5), Yuan teaches an aqueous composition comprising a β-sitosterol ester (a hydrophobic nutrient ester) associated with fatty acid methyl esters of canola oil (fatty acids ranging from C_6 to C_{12}), polysorbate 60 (a dispersion agent- surfactant; a sorbitan monostearate) and water.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kropf et al. (B) in view of Ozawa et al. (P) and Hendler et al. (F).

Applicant's claimed invention was set forth above.

The teachings of Kropf are set forth above. Kropf teaches the claimed aqueous dispersion except for wherein the hydrophobic nutrient in ester form associated with a dispersion aid is either Coenzyme Q_{10} or isoflavones, and a mixture of any of the foregoing esters. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the aqueous suspension of hydrophobic nutrients taught by Kropf by adding an ester of Coenzyme Q_{10} and/or an ester of isoflavones to provide the claimed invention because Ozawa and Hendler teach esters of the claimed ingredients, which are soluble in aqueous solutions and which have beneficial functional effects. Firstly, Ozawa teaches a composition comprising an ester of coenzyme Q10 (ubidecarenone) having improved solubility and bioavailability, wherein coenzyme Q10 is dissolved or dispersed in a fatty group. On page 2, lines 6-17, Ozawa teaches adding a middle fatty chain monoglycerine ester to coenzyme Q10 to make to improve the absorption of the ingredient when orally administered. Ozawa further teaches adding a vegetable oil to make an

admixture. For example, see Example 2 wherein Ozawa teaches heating and dissolving coenzyme Q10 in an admixture of monoglycerin caprate ester (nutrient ester associated with a dispersion aid) and soy bean oil (dispersion aid- triglyceride) to prepare a ubidecarenone ester solution, which is used in the making of medicines to improve cardiac functions. Secondly, Hendler teaches esters of soybean isoflavones, such as genistein, which are used in the making of aqueous solutions (See Figure 1). On page 1, in [0010] to [0011], Hendler teaches that the esterified isoflavones of his invention provide increased bioavailability of isoflavones and have good biocompatibility (see [0020]). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the Coenzyme Q_{10} ester and/or the isoflavone ester taught by Ozawa and Hendler to the aqueous suspension taught by Kropf to provide the claimed invention because Ozawa teaches that when a middle chain fatty acid monoglycerine ester group and a vegetable are added to coenzyme Q10, the oral absorption of coenzyme Q10 improves, and that hydroxypropyl cellulose can be evenly dispersed in an admixture solution of an ester of coenzyme Q10; and, Hendler teaches suggests that esterified isoflavones can be administered in the treatment of various disease conditions, as set forth on page 4, in [0050] to [0051].

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old

ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 2, 4, 5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mikkonen et al. (N) or Philip (A) or van Amerongen et al. (D) or Emodi et al. (E) or Patrick et al. (O) or Yuan et al. (C) in view of Ozawa et al. (P) and Hendler et al. (F).

Applicant's claimed invention was set forth above.

The teachings of Mikkonen, Phllip, van Amerongen, Emodi, Patrick,Yuan are set forth above. Neither Mikkonen, Philip, van Amerongen, Emodi, Patrick nor Yuan teach an aqueous suspension wherein the hydrophobic nutrient in ester form associated with a dispersion aid is either Coenzyme Q_{10} ester or an isoflavone ester, and a mixture of any of the foregoing esters. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify any of the the aqueous suspension of hydrophobic nutrients taught by either

Mikkonen, Philip, van Amerongen, Emodi, Patrick or Yuan by adding an ester of Coenzyme Q_{10} and/or an ester of isoflavones to provide the claimed invention because Ozawa and Hendler teach esters of the claimed ingredients, which are soluble in aqueous solutions and which have beneficial functional effects. Firstly, Ozawa teaches a composition comprising an ester of coenzyme Q10 (ubidecarenone) having improved solubility and bioavailability, wherein coenzyme Q10 is dissolved or dispersed in a fatty group. On page 2, lines 6-17, Ozawa teaches adding a middle fatty chain monoglycerine ester to coenzyme Q10 to make to improve the absorption of the ingredient when orally administered. Ozawa further teaches adding a vegetable oil to make an admixture. For example, see Example 2 wherein Ozawa teaches heating and dissolving coenzyme Q10 in an admixture of monoglycerin caprate ester (nutrient ester associated with a dispersion aid) and soy bean oil (dispersion aid- triglyceride) to prepare a unibecarenone solution, which is used in the making of medicines to improve cardiac functions. Secondly, Hendler teaches esters of soybean isoflavones, such as genistein, which are used in the making of aqueous solutions (See Figure 1). On page 1, in [0010] to [0011], Hendler teaches that the esterified isoflavones of his invention provide increased bioavailability of isoflavones and have good biocompatibility (see [0020]). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the Coenzyme Q_{10} ester and/or the isoflavone ester taught by Ozawa and Hendler to the aqueous suspension taught by Kropf to provide the claimed invention because Ozawa teaches that when a middle chain fatty acid monoglycerine ester group and a vegetable are added to coenzyme Q10, the oral absorption

of coenzyme Q10 improves, and that hydroxypropyl cellulose can be evenly dispersed in an admixture solution of an ester of coenzyme Q10; and, Hendler suggests that esterified isoflavones can be administered in the treatment of various disease conditions, as set forth on page 4, in [0050] to [0051].

Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

April 2, 2003

Michele C. Flood

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PATENT EXAMINER